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REMARKS

Claims 1, 2, 4, 5, 7-11, 13, and 15-22 are pending in the present application. By virtue of this response, claims 1 and 11 have been amended. No claims have been canceled and no new claims have been added. No new matter has been added. Accordingly, claims 1, 2, 4, 5, 7-11, 13, and 15-22 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Rejections under 35 U.S.C. §112, Second Paragraph**Claims 1, 2, 4, 5, 7-11, 13, and 15-22**

Claims 1, 2, 4, 5, 7-11, 13, and 15-22 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. Specifically, with respect to claims 1 and 11, the Office Action asserts that the term "likelihood" renders the claims vague and indefinite. The Office Action also asserts that the phrase "above about" in those same claims renders them indefinite. Applicant strongly disagrees.

With respect to the use of the term "likelihood," Applicant notes that claims 1 and 11 have been amended in order to more clearly indicate that the recitation of "any nasal irritation or coughing caused by the fine mist spray is thereby reduced" is a positive limitation. In making these amendments, the term "likelihood" has been removed from these claims. Therefore, the rejection of claims 1, 2, 4, 5, 7-11, 13, and 15-22 based on the term "likelihood" is moot. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

With respect to the use of the phrase "above about," Applicant notes that the use of the term "about" does not render a claim indefinite. As the MPEP describes, the fact that claim language includes terms of degree, does not automatically render the claims indefinite under 35 U.S.C. §112. See MPEP 2173.05(b) (citing *Seattle Box Co. v. Industrial Crating & Packing, Inc.* 731 F.2d 818,

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221 USPQ 568 (Fed. Cir. 1984)). The acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed in light of the specification. *Id.*

In this respect, Applicant notes that the term "about" has consistently been held by the courts to be clear and definite, because one having ordinary skill in the art would know how to detect infringement. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Indeed, even the USPTO seems to be in agreement with the courts, as a quick search of issued U.S. patents having the term "about" in the claims, resulted in 788,635 patent hits. Even assuming that only 10% of these patents use the term "about" as a relative measure, there would still be 78,863 issued patents having "about" as a relative measure in their claims. Clearly the patent office would not allow 78,863 patents having claims that were invalid for indefiniteness.

As supported by the illustrative patent numbers discussed above, the term "about" has been repeatedly used throughout claims in application after application, in order to help minimize the risk of an applicant being rigidly bound by a fixed number. Indeed, not allowing the term "about" to be used to indicate some slight variability about a number, would severely restrict the scope of the claims. Here, the pH is above "about 5." One having ordinary skill in the art would know that they could not avoid infringement by simply changing the pH to 5.1. Similarly, one having ordinary skill in the art reading the claim would know that they could not avoid infringement by simply changing the pH to 4.9. Indeed, the specification is clear on this matter, it states, "it is preferable that the spray have a pH above about 4.5, usually about 4.5 to about 7.5." *See* Applicant's specification pg. 7. Because one having ordinary skill in the art would know whether or not they would infringe Applicant's claims by altering the pH of the solution, the rejection is improper and should be withdrawn.

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Rejections Under 35 U.S.C. §103(a)Claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20

Claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak (DE003127590 A1) in view of U.S. Patent No. 5,976,521 to Briggs et al. ("Briggs") and Stone U.S. Patent No. 4,322,020 to Stone, ("Stone").

On April 12, 2004, the undersigned had a telephone interview with Examiners Yu and Padmanabhan. Agreement on the merits regarding the outstanding rejections was not reached. During that telephone interview, the undersigned described each and every element of independent claim 1, (from which the remaining claims directly or indirectly depend) and noted that the references cited by the Office Action fail to satisfy the requirements for a *prima facie* showing of obviousness as required by MPEP §2143.

As explained during the telephone interview, claim 1 comprises the following elements:

- 1) fine mist pump spray;
- 2) fine mist pump spray having no propellant;
- 3) fine mist pump spray adapted only for administration to non-facial body skin;
- 4) fine mist spray comprising a solution of salicylic acid;
- 5) the salicylic acid constitutes from about 0.01% to about 20% by weight of the solution;
- 6) the solution of salicylic acid having a pH of above about 5; and
- 7) any nasal irritation or coughing caused by the fine mist spray is thereby reduced.

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In order to set forth a *prima facie* case of obviousness, the references must teach or suggest all the claim elements, there must be some suggestion or motivation to modify the references or combine their teachings, and there must be a reasonable expectation of success, *see* MPEP §2143. Here, the references fail to meet any of the three requirements for a *prima facie* showing.

For example, the references fail to teach each and every claim element. First, none of Kozak, Briggs, or Stone teach a fine mist spray "adapted only for administration to non-facial body skin." Similarly none of Kozak, Briggs, or Stone teach a fine mist spray having the properties of claim 1 where "any nasal irritation or coughing caused by the fine mist spray is thereby reduced." Indeed, the Office Action completely fails to address how the art made of record teaches or even suggest these elements. This is not surprising because during the above-mentioned telephone interview, the Examiners took the view that neither of these elements were "true limitations" of claim 1. Specifically, the Examiners asserted that the "adapted only for non-facial body skin" limitation was merely a recitation of an intended use, and that the limitation of "any nasal irritation or coughing caused by the fine mist spray is thereby reduced" was an inherent property of the claimed fine mist spray. Similar assertions appear in the written Office Action. Applicant strongly disagrees.

First, the limitation that the fine mist spray be "adapted only for non-facial body skin" for treatment of non-facial acne or acneform, is not merely an intended use of the claim. As explained in the MPEP §211.02, the determination of whether preamble limitations are statements of use can only be resolved by reviewing the entire record to gain an understanding of what the inventor actually invented and what the inventor "intended to encompass by the claim." *See* MPEP §211.02 (emphasis added). Here, the inventor has made it clear (through discussions with the Examiners via the undersigned, through a detailed discussion of the non-facial use of the spray in the specification, and through detailed instructions distributed with the product indicating that the spray not be applied to the face) that the spray being adapted for application to non-facial body skin for the treatment of non-facial acne, is a part of her invention. It is clearly the Applicant's intention that this feature be encompassed by claim 1.

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The art made of record completely fails to address this limitation. Not surprisingly, the solutions taught in the art made of record are not capable of being adapted for "non-facial" use as recited in claim 1. As the MPEP describes, in situations where the art of record cannot perform the functions of the claimed use, then the use limitation must be given weight, and consequently, must be considered when trying to establish that each and every limitation has been taught. *Id.*

The Office Action is similarly flawed in completely ignoring, or considering inherent, the limitation of "any nasal irritation or coughing caused by the fine mist spray is thereby reduced." Indeed, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See MPEP §2112 (emphasis added). To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by a person of ordinary skill. *Id.* In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. *Id.* (emphasis added).

The statement in the Office Action stating that this limitation is "viewed [as] a property that is necessarily present in a composition comprising salicylic acid which has [a] pH above about 5" is insufficient. Similarly, the Examiners' abstract suggestion during the telephone interview that one having ordinary skill in the art would know that increasing the pH of an acid would cause less irritation is insufficient to establish that a fine mist spray solution of salicylic acid having a pH above about 5 would reduce any nasal irritation or coughing caused by the fine mist spray. These statements are particularly insufficient in view of Dr. Howard Maibach's declaration noting that, "it was not obvious to me, nor do I believe it would have been obvious [to] others, that...increasing the pH of the formulation—as Ms. Baker ultimately did—would significantly reduce these symptoms" (see Declaration of Howard Maibach, M.D. ¶ 5(b) submitted with Applicant's response to Office Action dated Nov. 4, 2003). Dr. Maibach, unlike the Examiners, is a leader in the dermatology field. If the Examiners wish to continue to rely on the theory of inherency, evidence should be submitted in the record and used to support that theory, so that Applicant can adequately respond.

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Until then, it is clear that the art made of record fails to teach or suggest each and every limitation of the presently rejected claims. Accordingly, the rejection of claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 under 35 U.S.C. §103(a) are improper and should be withdrawn.

Claims 9 and 10

Claims 9 and 10 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak, Briggs, and Stone as applied to claims 1, 2, 4, 5, 7-8, 10, 11, 13, 15-17, and 20 as above, and further in view of U.S. Pat. No. 5,612,324 to Guang Lin et al. ("Guang Lin"). Guang Lin was discussed in detail in Applicant's prior office action response dated March 10, 2003. It was noted there, that Guang Lin adds little to the teaching of Briggs. Indeed, Guang Lin fails to cure the deficiencies mentioned above, and therefore, for at least those reasons mentioned above, the rejections of claims 9 and 10 over Kozak, Briggs, Stone and Guang Lin, should be withdrawn.

Claims 21 and 22

Claims 21 and 22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak, Brigg, and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 as above, and further in view of U.S. Pat. No. 5,759,559 to Fitzjarrell ("Fitzjarrell"). Fitzjarrell was discussed in detail in Applicant's prior office action response dated March 10, 2003. In that response, Applicant described that not only did Fitzjarrell fail to teach or suggest each and every element, but that Fitzjarrell actually teaches away from the claimed invention.

Indeed, Fitzjarrell describes a method for treating acne on the "O or elliptically shaped area of the face that includes the nose and chin" using a topical spray of niacinamide with an oral supplement comprising lysine, selenium, zinc, and chromium (see col. 1, lines 38-40 and col. 2, lines 8-11). Fitzjarrell completely fails to describe a fine mist spray of salicylic acid solution adapted only for application to non-facial body skin, whereby any nasal irritation or coughing caused by the fine mist spray is thereby reduced. In addition, as Applicant noted in her March 3, 2003 response, Fitzjarrell expressly states that salicylic acid acne treatments are "often unsuccessful

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and may have significant side effects" (*see* background section). Accordingly, one having ordinary skill in the art would not even look to the teachings of Fitzjarrell to develop the present invention.

Fitzjarrell fails to teach or suggest each and every element of claim 1, and in fact, teaches away from any such combination. Therefore, the rejections of claims 21 and 22 over Kozak, Briggs, Stone and Fitzjarrell, should be withdrawn.

Claim 19

Claim 19 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Kozak, Briggs, and Stone as applied to claims 1, 2, 4, 5, 7, 8, 10, 11, 13, 15-17, and 20 above, and further in view of Sciarra (Remington: Practice of Science and Pharmacy). Claim 19 incorporates into its body, the limitations of 1. The rejection of claim 1 based on Kozak, Briggs, and Stone was discussed in detail above. Sciarra fails to cure this deficiency. Indeed, at best, Sciarra merely teaches the general use of aerosol devices for administering cosmetics. Accordingly, the rejection of claim 19 over Kozak, Briggs, Stone, and Sciarra, is improper and should be withdrawn.

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CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 425802000200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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